

COMPLETE LISTING OF CLAIMS

204-001

Application Number 10/603,311

WE CLAIM:

1. (original) A transdermal composition for the relief of pain in a subject comprising:
amitriptyline, clonidine, ketamine and an anti-inflammatory in a base.
2. (withdrawn) A transdermal composition as in claim 1, wherein said base is pentravan gel.
3. (withdrawn) A transdermal composition as in claim 1, wherein said base is 80% by weight pleuronic gel and 20% by weight lipoil.
4. (original) A transdermal composition as in claim 1, wherein said amitriptyline is between 2% and 4% by weight, preferably 4%.
5. (original) A transdermal composition as in claim 1, wherein said clonidine is between 0.2% and 0.5% by weight, preferably 0.5%.
6. (original) A transdermal composition as in claim 1, further comprising gabapentin.
7. (original) A transdermal composition as in claim 6, wherein said gabapentin is between 5% and 15% by weight, preferably 5%.
8. (original) A transdermal composition as in claim 1, wherein said ketamine is between 5% and 20% by weight, preferably 15%.
9. (original) A transdermal composition as in claim 1, wherein said anti-inflammatory is ketoprofen between 2% and 6% by weight, preferably 5%.

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65. (original) A transdermal composition for the relief of pain in a subject comprising:

4% by weight amitriptyline, 0.5% by weight clonidine, 15% by weight ketamine, and 5% by weight ketoprofen in a base.

66. (currently amended) A transdermal composition as in claim 65, further comprising an anti-inflammatory, wherein said anti-inflammatory is ibuprofen between 15% by weight and 22% by weight, preferably 20% by weight.

67. (original) A transdermal composition as in claim 65, further comprising 5% by weight gabapentin.

68. (new) A transdermal composition for the relief of pain in a subject comprising:

5 amitriptyline in amount between 2% and 4% by weight, clonidine in amount between 0.2% and 0.5% by weight, ketamine in an amount between 5% and 20% by weight, an anti-inflammatory, wherein said anti-inflammatory is ketoprofen in an amount between 2% and 6% by weight and a base.

69. (new) A transdermal composition as in claim 68, wherein said clonidine is about 0.5% by weight.

70. (new) A transdermal composition as in claim 68, further comprising gabapentin.

71. (new) A transdermal composition as in claim 70, wherein said gabapentin is between 5% and 15% by weight, preferably 5%.

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72. (new) A transdermal composition as in claim 68, wherein said ketamine is about 15% by weight.

73. (new) A transdermal composition as in claim 68, wherein said ketoprofen is about 5% by weight.

74. (new) A transdermal composition for the relief of pain in a subject comprising:

amitriptylline in an amount about 4% by weight, clonidine in an amount about 0.5% by weight, gabapentin in an amount about 5% by weight, ketamine in an amount about 15% by weight, an anti-inflammatory, wherein said anti-inflammatory is ketoprofen in an amount about 5% by weight and a base.

75. (new) A transdermal composition for the relief of pain in a subject comprising:

amitriptylline in amount between 2% and 4% by weight, clonidine in amount between 0.2% and 0.5% by weight, gabapentin in an amount between 5% and 15% by weight, ketamine in an amount between 5% and 20% by weight, an anti-inflammatory, wherein said anti-inflammatory is ketoprofen in an amount between 2% and 6% by weight and a base.

76. (new) A transdermal composition as in claim 75, wherein said clonidine is about 0.5% by weight.

77. (new) A transdermal composition as in claim 75, wherein said gabapentin is about 5% by weight.

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78. (new) A transdermal composition as in claim 75, wherein said ketamine is about 15% by weight.

79. (new) A transdermal composition as in claim 75, wherein said ketoprofen is about 5% by weight.

80. (new) A transdermal composition for the relief of pain in a subject comprising: 4% by weight amitriptyline, 0.5% by weight clonidine, 15% by weight ketamine, 5% by weight ketoprofen and an anti-inflammatory in a base.

81. (new) A transdermal composition as in claim 80, wherein said anti-inflammatory is ibuprofen between 15% by weight and 22% by weight, preferably 20% by weight.

82. (new) A transdermal composition as in claim 80, further comprising 5% by weight gabapentin.

83. (new) A transdermal composition for the relief of pain in a subject comprising: 4% by weight amitriptyline, 0.5% by weight clonidine, 5% by weight gabapentin, 15% by weight ketamine, 5% by weight ketoprofen and an anti-inflammatory, wherein said anti-inflammatory is 20% by weight ibuprofen in a
5 base.

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[023] According to a preferred embodiment, the base may be pentravan® gel. Pentravan® gel is an emollient which softens and moisturizes the skin. Emollients may be used as lubricants to treat or prevent dry, itchy skin and minor skin irritations. The base may also be a base comprised of approximately 80% by weight pleurine pluronic gel and approximately 20% by weight lipoil™. The proper base is extremely important, as it acts as a vehicle that allows the various drug components to penetrate the skin. Traditional cream or ointment bases would not be effective. The amitriptyline may be between 2% and 4% by weight, preferably 4%. Amitriptyline is a tricyclic antidepressant with proven efficacy on neuropathic pain when administered orally. However, oral administration has many serious side effects, especially in the elderly population. This may include anticholinergic effects, such as tachycardia, dry mouth and severe sedation. There may be clonidine between 0.2% and 0.5% by weight, preferably 0.5%. Clonidine is an antihypertensive medicine. The composition may also have gabapentin, which may be between 5% and 15% by weight, preferably 5%. Gabapentin is an anticonvulsant medication. The ketamine may be between 5% and 20% by weight, preferably 15%. Ketamine is generally administered by IV for general anesthesia. It has NMDA inhibitor properties and is effective in controlling pain at spinal cord level. The anti-inflammatory may be ketoprofen between 2% and 6% by weight, preferably 5%.

[024] According to one embodiment, a transdermal composition for the relief of pain in a subject comprising: amitriptyline, clonidine, gabapentin and ketamine in a base. The base may be pentravan® gel or a composition made of 80% by weight pleurine pluronic gel and 20% by weight lipoil™. The composition may also comprise 5% to 10% by weight lidocaine. There may also be EMLA. EMLA is a local anesthetic usually used to numb the skin to pain from injections. It is also sometimes used to reduce pain associated with tattooing, electrolysis, laser hair removal, etc. It is generally comprised of lidocaine and prilocaine. The amitriptyline may be 2% to 4% by weight, clonidine may be 0.2%

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to 0.5% by weight, gabapentin may be 6% to 12% by weight, the ketamine may be 1% to 20% by weight.

[025] By way of example, an order for 60 grams of neuropathy cream may be prepared by obtaining 1.2 grams amitriptyline (2% by weight), 120 mg clonidine (0.2% by weight), 9 grams gabapentin (15% by weight) 3.6 grams ketamine (6% by weight), and 4.2 grams EMLA cream (7% by weight). The powders may be mixed (e.g. in an EMP Jar) and dissolved with a small amount of grain alcohol (~90% ethanol). Pentravan® Gel may be added to make 60 grams. Finally and unguator is used to mix the final product into a very fine, smooth crème.

[026] According to another embodiment, a transdermal composition for the relief of pain in a subject is disclosed comprising: amitriptyline, cyclobenzaprine, dexamethazone, gabapentin and an anti-inflammatory in a base. The base is may be pentravan gel or a base made of 80% by weight pleurine pluronic gel and 20% by weight lipoil™. The amitriptyline may be between 2% and 4% by weight, the cyclobenzaprine may be between 2% and 4% by weight, the dexamethazone may be between 0.2% and 0.5% by weight, and the gabapentin may be between 6% and 12% by weight. The anti-inflammatory may be ibuprofen being between 18% and 22% by weight. The anti-inflammatory may also be ketoprofen being between 2% and 4% by weight.

[027] Another embodiment provides a transdermal composition for the relief of pain in a subject comprising: amitriptyline, cyclobenzaprine, dexamethazone, gabapentin, an anti-inflammatory and a local anesthetic in a base. As previously, the base may be pentravan® gel or a base made of 80% by weight pleurine pluronic gel and 20% by weight lipoil™. The amitriptyline may be between 2% and 4% by weight, the cyclobenzaprine may between 1% and 3% by weight, preferably 2%, the dexamethazone may be between 0.3% and 0.5% by weight, preferably 0.4%. The gabapentin may be between 6% and 12% by weight. The anti-inflammatory may be between 15% by weight and 22% by

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weight ibuprofen, preferably 20% by weight. The anti-inflammatory may also be ketoprofen between 2% by weight and 4% by weight. The local anesthetic may be between 5% by weight and 10% by weight lidocaine. Lidocaine is generally used in injectable form for local, regional and neuroaxial anesthesia. While Lidocaine has been used as a topical agent, it has limited benefit when used as a sole agent. The local anesthetic may also be between 5% by weight and 10% by weight EMLA, preferably 7% by weight. EMLA is a cream, and is no longer readily available. However, the term is intended to denote a cream that has 2.5% Lidocaine and 2.5% Prilocaine.